APPENDIX 3.8.8.

GUIDELINES ON SURVEILLANCE FOR CLASSICAL SWINE FEVER

Article 3.8.8.1.

Introduction

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Surveillance for CSF should be in the form of a continuing programme designed to either establish that a population is free from CSFV infection (either the whole country ~~or~~ a *zone* ~~within the country is free from CSFV infection~~ or a compartment) or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on disease spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent infections, the occurrence of persistent and chronic infections, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

Rationale: This appendix on CSF surveillance has two main objectives, which are 1) to detect CSF in a disease free population, and 2) to document the absence of CSF in a disease free population. The United States believes these should be explicitly stated. For detection of CSF, it is generally best to conduct targeted surveillance, whereas, for disease freedom demonstration, it is best to conduct surveillance that is representative of the population at hand.

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Article 3.8.8.3.

Surveillance strategies

1. Introduction

There are two basic strategies that can be employed for CSF surveillance depending on the purpose of the country for seeking recognition of freedom from CSF. In countries historically free of CSF, surveillance programs should be designed to detect the introduction of CSFV into domestic or wild swine. The optimal strategy to meet this objective is most often targeted surveillance.

The ~~target~~ population ~~for~~ covered by surveillance aimed at ~~identifying~~ detecting *disease* and *infection* should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

~~Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy.~~ Surveillance is targeted to the pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks,* pig movements and demographics, etc.

Rationale: See comments in box above.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent infections and difficulties associated with differential diagnosis of other diseases, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

The country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Appendix 3.8.1. and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member Country wishes to apply for recognition by other Member Countries of a specific *zone* within the country as being free from CSFV infection, the design of the

surveillance strategy and the basis for any sampling process would need to be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are ~~key~~ factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

2. Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF has two aims: a) to shorten the period between introduction of CSF virus into a disease free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF.

~~One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals.~~ The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring.

Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals. Otherwise close physical examination of susceptible animals is useful as a selection criteria for CSF surveillance, particularly in diagnostic laboratories or slaughter establishments or when applied to high risk populations such as swill feeding operations.

~~In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF. In *zones* or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.~~

~~Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring.~~ The difficulties in detecting chronic disease manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such animals may, however, escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and disease status in neighbouring *zones* or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological

screening as the best method for surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of disease. Herds predominated by adult animals, such as nucleus herds and artificial insemination studs, are particularly useful groups to monitor, since infection by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of disease if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing disease. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in disease free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterization.

Comment/Rationale: The text under this section (Clinical and virological surveillance) was slightly rearranged to remove some of the redundant language, and make the main points clearer. In addition, a couple of sentences were added to clarify the role of clinical signs in surveillance activities.

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Article 3.8.8.4.

Country or zone historically free of CSF ~~in domestic and wild pigs~~

~~1. Historically free status~~

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) an increase in the volume of imports or a change in their country or *zone* of origin;

c) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones;*

d) an increased entry from, or exposure to, infected wild pig populations of adjacent countries or *zones.*

Rationale: The United States recommends adding the word "infected" to item d) above. Many CSF free countries border other CSF free countries or zones (also free of CSF in their wild populations), and as such do not present an increased risk.

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Article 3.8.8.6.

Recovery of free status

1. Countries or zones seeking re-establishment of freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7., a country seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active surveillance programme ~~for CSF as well as~~ to demonstrate absence of CSFV infection.

Populations under this surveillance programme should include~~, but not be limited to~~:

a) *establishments* in the ~~area~~ proximity of the *outbreak;*

b) *establishments* epidemiologically linked to the *outbreak;*

c) animals used to re-populate affected *establishments* and any *establishments* where contiguous
culling is carried out;

d) wild pig populations in the ~~area~~ proximity of the *outbreak*.

Comment/note: replaced "area" with "proximity' to be consistent with point a).

In all circumstances, a Member Country seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of ~~an~~ active and passive surveillance ~~programme~~ programmes in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

Rationale: A single program cannot be both active and passive. Hence, we recommend the adjustment in text.

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